K110210

This 510k summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

APR 20 2011

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Device Name and Classification	
Trade name/Product Name:	Saturn 8000-GS System
Classification name:	Stationary X-ray System
Common name:	General purpose diagnostic X-ray System
Product Code:	MQB
Regulation Number	892.1650

Date Prepared	2011.01.12

Substantial Equivalence claimed to:	New Medical Saturn 9000 System

Device Description

The "Digital X-ray Capture Device (Saturn 8000-GS System)" (as Saturn 8000-GS System) is equipped with digital detector, X-ray generator interface, and image acquisition workstation. The digital detector is a flat panel detector. The input X-ray photons are absorbed in scintillator layer that creates a visible light photon, and then the photon is absorbed in TFT-array to create an electrical charge which is representation of the X-ray input. The charge is read-out by a matrix scan of the array that converts the charges into a modulated electrical signal. X-ray exposure can be triggered by detector, which initiate the exposure signal to the generator; or the exposure signal is triggered by the generator itself and the detector is acted as bucky receptor. The connection between generator and detector is via the hardware interface box (HIB), which can also connect the hand switch. The Saturn 8000-GS System contains the operation workstation software, which is installed on acquisition workstation ("AWS"), which contains monitor, keyboard and mouse, computer, electronics, and accessory storage. The resultant output signal can be transmitted to remote viewing sites, and/or it can be stored electronically for later viewing. The AWS is used for image acquisition, processing, and display. The AWS can also be used for database management and can send images to archive, review or filming.

Indications for Use

The Saturn 8000-GS system generates digital X-ray images that can be used for general X-ray system except fluoroscopic, angiographic, and mammographic applications. The Saturn 8000-GS system can interface to traditional X-ray generator and get digital X-ray image. The Saturn 8000-GS is intended to be used in same clinical application as traditional film-screen based general radiography system.

Substantial Equivalence

The Saturn 8000-GS System is substantially equivalent to the commercially available New Medical Saturn 9000 system cleared on December 11, 2006 via 510k K063710. Bench testing and electrical safety further substantiate equivalence to the predicate. The Saturn 8000-GS System utilizes the Varian PaxScan 4336R panel while the New Medical Saturn 9000 System utilizes the DRTech FDXD1417 panel to acquire image.

General Safety and Effectiveness Concerns

Electrical, mechanical safety and performance testing according to standard EN/IEC 60601-1, EN/IEC 60601-1-1, EN/IEC 60601-1-3 and EN/IEC 60601-2-32 was performed, and EMC testing was conducted in accordance with standard EN/IEC 60601-1-2(2007). All test results were satisfactory.

Conclusion

The results of all testing demonstrate that the Satum 8000-GS does not raise any new significant issues of safety, effectiveness or performance of the device when compare to the existing predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Jun-Hstung Lin
Manager
New Medical Co., Ltd.
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AUG 23 2013

Re: K110210
Trade/Device Name: Saturn 8000-GS System
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: January 12, 2011
Received: January 25, 2011

Dear Mr. Lin:

This letter corrects our substantially equivalent letter of April 20, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K110210

Device Name: Saturn 8000-GS System

Indications For Use:

The Digital X-ray Capture Device Saturn 8000-GS Systems is indicated for use in general radiographic images of human anatomy. It is intended to replace radiographic film/screen systems in all general-purpose diagnostic procedures (excluding fluoroscopic, angiographic, and mammographic applications).

Prescription Use ___v___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~ OIVD

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety